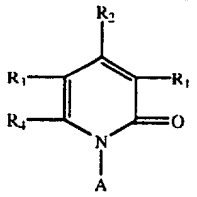
The differences in the concentrations of pirfenidone which pharmacologically arrest the proliferation of neoplasia cells and the pirfenidone concentration which kills neoplasia cells affords a larger margin of safety for patients, (Raghu, G., et al., *Amer. J. Resp. and Critical Care Med.*, 1997, Vol. 155:A741), and thereby distinctly reduces the incidence of serious adverse effects experienced by patients during treatment, as compared to treatment with currently conventional anti-neoplasia agents.

The intracellular action of pirfenidone in (1) arresting the proliferation and (2) subsequent destruction of the abnormal or neoplastic cells takes place in the cell nucleus and directly involves the signaling via the specific gene activated proteins (for example, p53, Rb, WT1, etc.) and ameliorating or blocking the impact of such gene proteins on the cell transcription apparatus and cyclins. These specific gene proteins act on the check points of the cell cycle to prevent or correct the aberrant gene protein signals impacting on the cyclins and check points.

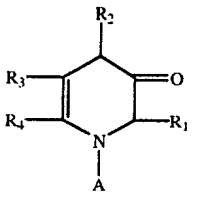
It is estimated that the effective dosage of one or more N-substituted 2-(1H) pyridone(s) and/or N-substituted 3-(1H) pyridone(s) in practicing the present invention is from about 250 to about 750 mg/kg of body weight per day, which dosage may be taken in the diet.

The general structural formula of N-substituted 2-(1H) pyridones is:



where: R1 is selected from the group consisting of (1) an alkyl group, with R3 hydrogen, and (2) hydrogen, with R3 consisting of an alkyl group; A is an aryl group; and R2 and R4 are hydrogen.

The general structural formula for the N-substituted 3-1 (H) pyridones is:



where: R2 is selected from the group consisting of (1) an alkyl group, with R3 hydrogen, and (2) hydrogen, with R3 consisting of an alkyl group; A is an aryl group; and R1 and R4 are hydrogen.

Examples of the pyridone compounds which have been found or are believed to be effective in practicing the present invention include:

5-Methyl-1-phenyl-2-(1H) pyridone
5-Methyl-1-(3-nitrophenyl-2)-(1H) pyridone
5-Methyl-1-(4'-methoxyphenyl)-2-(1H) pyridone
5-Methyl-1-p-tolyl-2-(1H) pyridone
5-Methyl-1-(3'-trifluoromethylphenyl)-2-(1H) pyridone
1-(4'Chlorophenyl)-5-methyl-2-(1H) pyridone
5-Methyl-1-(2'-naphthyl)-2-(1H) pyridone

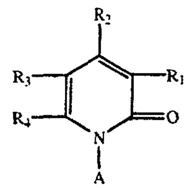
5-Methyl-1-('-naphthyl)-2-(1H) pyridone
3-Methyl-1-phenyl-2-(1H) pyridone
6-Methyl-1-phenyl-2-(1H) pyridone
3,6-Dimethyl-1-phenyl-2-(1H) pyridone
5-Methyl-1-(2'thienyl)-2-(1H) pyridone
1-(2'-Furyl)-5-methyl-2-(1H) pyridone
5-Methyl-1-(5'-quinolyl)-2-(1H) pyridone
5-Methyl-1-(4'-pyridyl)-2-(1H) pyridone
5-Methyl-1-(3'-pyridyl)-2-(1H) pyridone
5-Methyl-1-(2'-pyridyl)-2-(1H) pyridone
5-Methyl-1-(2'-quinolyl)-2-(1H) pyridone
5-Methyl-1-(4'-quinolyl)-2-(1H) pyridone
5-Methyl-1-(2'-thiazolyl)-2-(1H) pyridone
1-(2'-Imidazolyl) -5-methyi-2-(1H) pyridone
5-Ethyl-1-phenyl-2-(1H) pyridone
3-Ethyl-1-phenyl-2-(1H) pyridone
1-Phenyl-2-(1H) pyridone
1-(4'-Nitrophenyl)-2-(1H) pyridone
5-Methyl-3-phenyl-1-(2'-thienyl)-2-(1H) pyridone
5-Methyl-1-phenyl-3-(1H) pyridone
5-Methyl-1-(4'-methoxyphenyl)-3-(1H) pyridone
5-Methyl-1-p-tolyl-3-(1H) pyridone
1-(4'-Chlorophenyl)-5-methyl-3-(1H) pyridone
5-Methyl-1-(2'-naphthyl)-3-(1H) pyridone
4-Methyl-1-phenyl-3-(1H) pyridone
6-Methyl-1-pheyl-3-(1H) pyridone
5-Methyl-1-(2'-thienyl)-3-(1H) pyridone
1-(2'-Furyl)-5-methyi-3-(1H) pyridone
5-Methyl-1-(5'-quinolyl)-3-(1H) pyridone
5-Methyl-1-(3'-pyridyl)-3-(1H) pyridone
5-Methyl-1-(2'-pyridyl)-3-(1H) pyridone
5-Methyl-1-(2'-quinolyl)-3-(1H) pyridone
5-Ethyl-1-phenyl-3-(1H) pyridone
1-Phenyl-3-(1H) pyridone.

It will thus be seen that the objects set forth above, amoung those elucidated in, or made apparent from, the preceding description, are efficiently attained and, since certain changes may be made in the above compositions and methods without departing from the scope of the invention, it is intended that all matter contained in the foregoing disclosure shall be interpreted as illustrative only and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

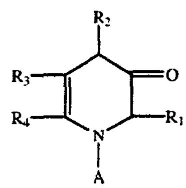
I claim:

1. A method of treating lymphomas, leukemias, and/or leiomyomas in a laboratory animal or a human, comprising: administering to said laboratory animal or said human an effective dose of a composition including one or more pharmaceutical substances selected from the group consisting of N-substituted 2-(1H) pyridones, N-substituted 3-(1) pyridones, and pharmaceutically acceptable salts thereof, wherein said 2-(1H) pyridiones have the following *general* structural formula:



where: R1 is selected from the group consisting of (1) an alkyl group, with R3 hydrogen, and (2) hydrogen, with R3 consisting of an alkyl group; A is an aryl group; and R2 and R4 are hydrogen;

and wherein said 3-(1H) pyridones have the following general structural formula:



where: R2 is selected from the group consisting of (1) an alkyl group, with R3 hydrogen, and (2)hydrogen, with R3 consisting of an alkyl group; A is an aryl group; and R1 and R4 are hydrogen.

2. A method, as defined in claim 1, wherein: said composition is administered orally or parenterally to said laboratory animal at a rate of from about 250 to about 750 mg/kg of body weight per day.

3. A method, as defined in claim 1, wherein: said composition is administered orally or parenterally to a human at a rate of from about 20 to about 60 mg/kg of body weight per day.

4. A method of treating lymphomas, leukemias, and/or leiomyomas in a laboratory animal or a human, comprising: administering to said laboratory animal or said human an

effective dose of a composition including one or more pharmaceutical substances selected from the group consisting of N-substituted 2-(1H) pyridones, N-substituted 3-(1H) pyridones, and pharmaceutically acceptable salts thereof, said N-substituted 2-(1H) pyridones and said N-substituted 3-(1H) pyridones being selected from the group consisting of: 5-methyl-1-phenyl-2-(1H) pyridone, 5-Methyl-1-(3-nitrophenyl-2)-(1H) pyridone, 5-Methyl-1-(4'-methoxyphenyl)-2-(1H) pyridone, 5-Methyl-1-p-tolyl-2-(1H) pyridone, 5-Methyl-1-(3'-trifluoromethylphenyl)-2-(1H) pyridone, 1-(4°Chlorophenyl)-5-methyl-2-(1H) pyridone, 5-Methyl-1-(2'-naphthyl)-2-(1H) pyridone, 5-Methyl-1-(1'-naphthyl)-2-(1H) pyridone, 3-Methyl-1-phenyl-2-(1H) pyridone, 6-Methyl-1-phenyl-2-(1H) pyridone, 3,6-Dimethyl-1-phenyl-2-(1H) pyridone, 5-Methyl-1-(2'thienyl)-2-(1H) pyridone, 1-(2'-Furyl)-5-methyl-2-(1H) pyridone, 5-Methyl-1-(5'-quinolyl)-2-(1H) pyridone, 5-Methyl-1-(4'-pyridyl)-2-(1H) pyridone, 5-Methyl-1-(3'-pyridyl)-2-(1H) pyridone, 5-Methyl-1-(2'-pyridyl)-2-(1H) pyridone, 5-Methyl-1-(2'-quinolyl)-2-(1H) pyridone, 5-Methyl-1-(4'-quinolyl)-2-(1H) pyridone, 5-Methyl-1-(2'-thiazolyl)-2-(1H) pyridone, 1-(2'-Imidazolyl)-5-methyl-2-(1H) pyridone, 5-Ethyl-1-phenyl-2-(1H) pyridone, 3-Ethyl-1-phenyl-2-(1H) pyridone, 1-Phenyl-2-(1H) pyridone, 1-(4'-Nitrophenyl)-2-(1H) pyridone, 5-Methyl-3-phenyl-1-(2'-thienyl)-2-(1H) pyridone, 5-Methyl-1-phenyl-3-(1H) pyridone, 5-Methyl-1-(4'-methoxyphenyl)-3-(1H) pyridone, 5-Methyl-1-p-tolyl-3-(1H) pyridone, 1-(4'-Chlorophenyl)-5-methyl-3-(1H) pyridone, 5-Methyl-1-(2'-naphthyl)-3-(1H) pyridone, 4-Methyl-1-phenyl-3-(1H) pyridone, 6-Methyl-1-phenyl-3-(1H) pyridone, 5-Methyl-1-(2'-thienyl)-3-(1H) pyridone, 1-(2'-Furyl)-5-methyl-3-(1H) pyridone, 5-Methyl-1-(5'-quinolyl)-3-(1H) pyridone, 5-Methyl-1-(3'-pyridyl)-3-(1H) pyridone, 5-Methyl-1-(2'-pyridyl)-3-(1H) pyridone, 5-Methyl-1-(2'-quinolyl)-3-(1H) pyridone, 5-Ethyl-1-phenyl-3-(1H) pyridone, and 1-Phenyl-3-(1H) pyridone.

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